ARTAS System

RESTORATION ROBOTICS

HOW TECHNOLOLGY IS CHANGING THE HAIR RESTORATION INDUSTRY

By Cindy L. Vandruff, MBA – Editor in Chief

Hair restoration has been a growing trend in the aesthetic industry for the last few decades, and there are estimated to be more than 800,000 hair restoration patients worldwide each year.[1] Strip-excision harvest, or the process of cutting a strip of skin out of the back of the head and then harvesting individual follicular units from the strip, has been the common practice in follicular unit transplantation. Over the last several years, advances have been made towards extracting single units of hair with tiny punches, or Follicular Unit Extraction (FUE). This coincides with a general movement in medicine towards less invasive procedures and reduced recovery times.

Hair restoration surgery by the most skilled physicians can produce incredibly natural hairlines such that even hairdressers cannot detect that surgery took place. However, FUE, the minimally invasive approach to extracting individual follicular units, remains a very tedious and precise art, resulting in very few surgeons feeling that they are able to dedicate the time and conquer the skills necessary to offer this procedure to their patients. "The typical barrier to entry has been two to three years of practice," commented James Harris, M.D. of Hair Sciences of Colorado (Denver, CO; www.hsccolorado.com). In FUE, a doctor is looking at numerous individual follicles of hair, magnified using loupes to the point of visibility. "The physician then has to decide, how deep should I go? What do I think the follicles

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are doing underneath? Which follicles should I extract, and how far apart should they be? These are all factors that every doctor is looking at for every follicular unit to be extracted," explains James Harris, M.D. "It is an incredibly complex analysis."

THE ARTAS SYSTEM

Restoration Robotics, Inc. (Mountain View, CA; www.artashair.com) has just resolved this complex analysis for doctors with the recent FDA clearance of the ARTAS System. "The theory behind applying robotic technology to FUE was that if you could actually remove all of the nuanced decisions regarding angles, directions, and so forth required by the physician and use technology to determine those factors, you could take a physician with little experience and after a couple of hours of training, he could produce grafts with the ARTAS System as good as mine are after eight years of experience," says James Harris, M.D. "The image-guided robotic arm is programmed with complex algorithms and sensors and is able to do with great precision what a physician can do only with extensive practice and some guess work."

"The procedure and work of the technology are really quite remarkable," James Harris, M.D. informs us. When a patient comes in, his hair is cut down to 1mm in length. This allows the imaging system to identify and map each follicular unit. The patient is then anesthetized and placed in the chair designed especially to be ergonomically

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comfortable for the patient. A specially designed device called a skin tensioner is then placed on the patient's scalp. This skin tensioner, which has fiducial markings as reference points, provides the mechanism by which the system tracks all of the follicular units, follows patient movement, and allows precise control of incision depth.

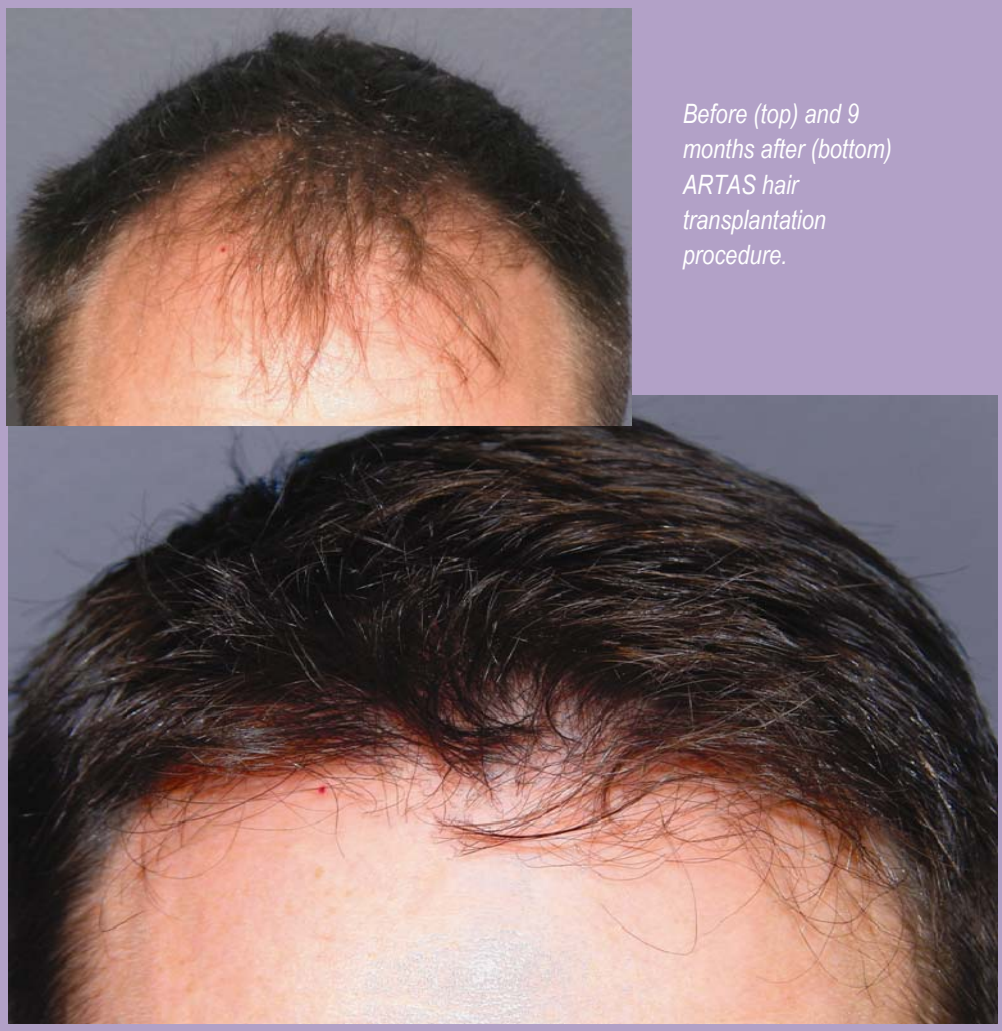
ARTAS SKIN TENSIONER

With the skin tensioner in place, the physician may press the "harvest" button. Red lights appear which heighten the contrast between the hair follicles and the skin, and the ARTAS System then analyzes them with assistance of a set of cameras. The technology determines the location, angle, and direction of each individual hair follicle; and via complex algorithms and computer programming, it is able to determine almost instantaneously the proper approach to harvest each follicular unit. The image-guided robotic arm begins harvesting the hair follicles in random patterns, according to the harvest spacing set by the physician. These random patterns make the procedure virtually undetectable after the wounds have healed. A sharp needle first scores the skin, and then the follicular unit is dissected with the more blunt punch. Light suction may be used to assist in elevating the follicular units from the skin, and the physician is able to extract and evaluate them. Once harvesting is complete in a certain area, the skin tensioner is moved to the next area of the scalp.

"Manual FUE is an incredibly tedious and precise process, and you can imagine the experience required to become proficient at it," relates James Harris, M.D. "Even for experienced physicians it is easy to become tired after a couple of hours, and then transection rates get worse. The ability to now use the ARTAS technology to do so much of the minute calculations and precision punching is an unparalleled aid in FUE."

IMAGE GUIDED SYSTEM

Miguel Canales, M.D., Medical Director for Restoration Robotics, described the clinical research carried out on the image-guided system. "There is not a lot of published data on transection rates with FUE, but it is considered that between 20-30% of follicles are unusable due



Before (top) and 9 months after (bottom) ARTAS hair transplantation procedure.

to being cut or damaged in some way. With the ARTAS System we consistently had transection rates of less than 10%." Canales' testing was conducted in multiple sites, with both physicians and technicians of all skill levels. Not only does the ARTAS System produce excellent quality grafts, it also allows the surgeon to work very quickly. A novice physician performing FUE manually may be able to extract 50-70 grafts in an hour. One who has been doing it for two years may be extracting around 200 grafts per hour. For a procedure that requires 1500 grafts, it is usually a prohibitively long surgery. "I can take that same surgeon who has been practicing for two years, train him for an hour to 90 minutes on the ARTAS System, and he will be able to extract 600-700 grafts an hour," reports James Harris, M.D.

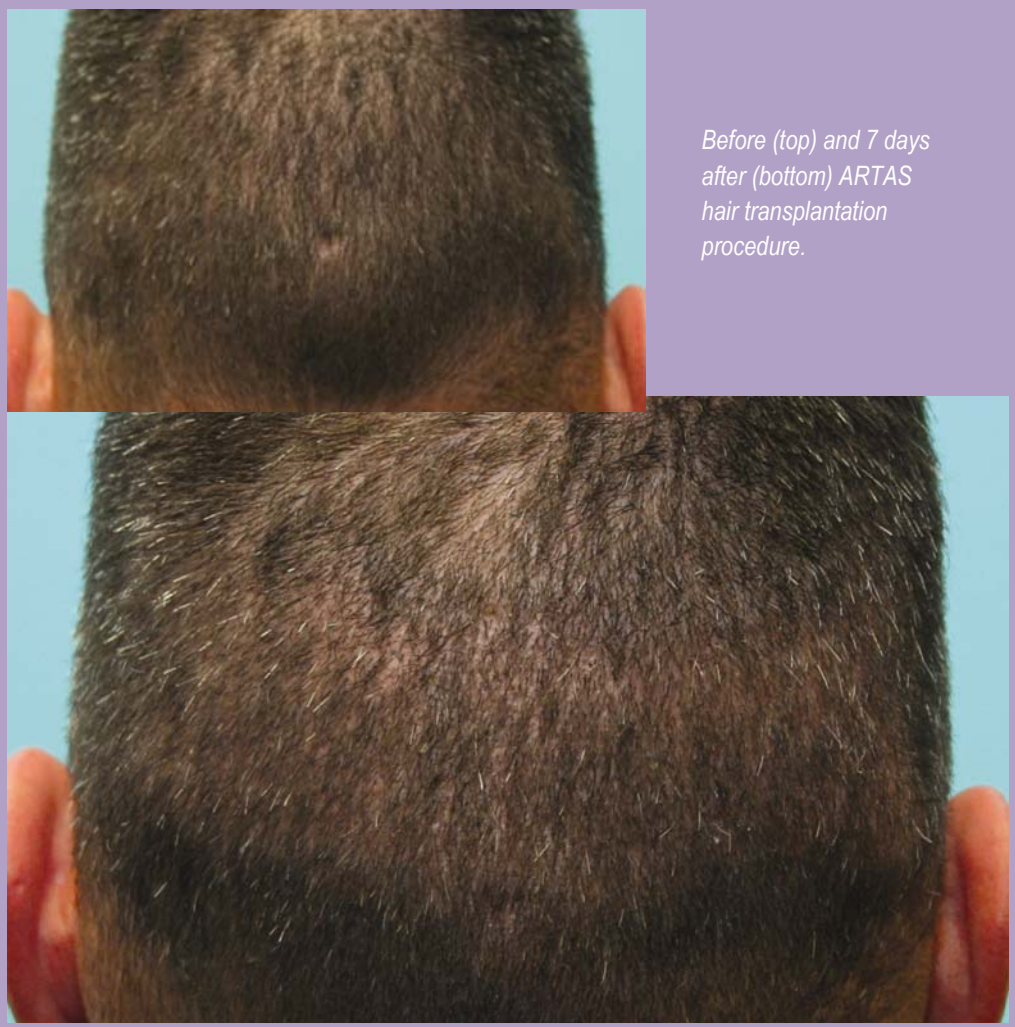
SYSTEM SAFETY

Developers of the ARTAS System did not just want it to be efficient and more effective; they were focused on the safety of the ARTAS System. "One of our design priorities was safety, so we have developed a number of attributes to make sure that the System is safe in the hands of trained physicians," explains Canales. The first of these is a built-in force sensor that constantly monitors the forces that are exerted by the tips of the punches. If the force goes above a certain threshold, the system backs away, prompting the physician to ensure that all is well before resuming treatment.

There are sensors around the casing of the mechanism itself, ensuring that if the casing touches the patient, the System automatically backs away from the patient. This prevents the patient from ever feeling as if they are being pushed. Another safety feature is the motion detector that is continually monitoring the patient. As the patient moves, it adapts or pauses until the physician can verify that the patient is ready to proceed. During the clinical trials of over 350 patients, no safety-related adverse events occurred.

"In addition to the sensors, the needles themselves have markings on them to indicate depth.

Photos and videos are constantly being taken of the procedure which the physician can view on the user interface. With simple arrows the physician can then indicate if the needles need to incise deeper into the skin or more shallow," explains Canales.



Before (top) and 7 days after (bottom) ARTAS hair transplantation procedure.

MEETING THE NEEDS OF PHYSICIANS AND PATIENTS

The ARTAS System has thus met the very important needs of both the physician and the patient in the hair restoration field. For physicians, it provides a very safe manner of consistently extracting a high volume of healthy, intact hair grafts in a shorter amount of time. The follicular units harvested with the ARTAS System require little or no trimming and are ready to implant immediately after harvesting, which helps enhance graft survival success rates and reduces the technician time. Reduced physician labor allows for more efficient appointment scheduling, and the significant reduction in the learning curve allows more physicians to offer the ARTAS procedure to their patients.

The advantages to the patient are also numerous. The ARTAS procedure does not require a strip excision and does not leave any staples or sutures. The procedure is minimally invasive, and patients are able to recover quickly. The ability to extract follicles more rapidly and precisely means less anesthesia for the patient, better re-growth rates for the grafts, and an overall shorter and more comfortable procedure.

The patients obtain a permanently robust and improved hairline, meeting their cosmetic goals in a very safe and effective manner. In addition, more physicians are able to offer FUE results in more options for patients demanding a safe, effective, and minimally invasive permanent hair restoration procedure. The ARTAS System, with its image-guided robotic arm, is truly an automated system under the control of a physician. "It has the capability to assist in making decisions about which grafts to extract, how to approach the grafts, and so forth. This is going to expand physicians' capability to provide quality surgery to their patients. That is what has been lacking in FUE." James Harris, M.D. continues, "When FUE first came out, doctors were getting bad grafts and giving their patients not exactly the greatest results, so a lot of people backed out of it. The beauty of this system is that doctors can now offer quality grafts, enhance patient outcomes, and not have to dedicate years to training in order to do so." Rigorously tested and developed in close collaboration with leading hair experts in clinical trials, the ARTAS image-guided system has been cleared for use by the FDA. Physicians and patients alike can now benefit from this minimally invasive, permanent solution to hair restoration.

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Reference

[1] International Society for Hair Restoration Surgery Census Results. Viewed online July 18, 2011. http://www.ishrs.org/PDF/ISHRS_2009_Census.pdf

About Restoration Robotics

Restoration Robotics, Inc., a privately held medical device company, is dedicated to revolutionizing the field of hair transplantation by developing and commercializing a state-of-the-art image-guided system (ARTAS™ System) that enables follicular unit extraction. **650.965.3612 www.artashair.com**